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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,423	03/10/2005	Albert Duranton	122005	2517

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,423	DURANTON ET AL.	
	Examiner	Art Unit	
	GINA C. YU	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-43* is/are pending in the application.

4a) Of the above claim(s) *14, 16-18, 22-25, 27-38, 42, 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-13,15,19-21,26 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *July 31, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on July 31, 2008. All objections made to the application with respect to formality, as indicated in the previous Office action dated February 4, 2008, are in view of the applicant's amendment and remarks. The claim rejections made under 35 U.S.C. 112, first and second paragraphs, are withdrawn in view of the applicant's claim amendment in part and of applicant's remarks in part. The claim rejection made under 35 U.S.C. 102 (b) indicated in the previous Office action is withdrawn in view of the present claim amendment. The claim rejection made under 35 U.S.C. 103 (a) indicated in the same Office action is withdrawn in view of the applicant's remarks.

Claims 1-6 and 8-43 are pending, of which claims 14, 16-18, 22-25, 27-38, 42-43 have been withdrawn from consideration due to restriction and species election requirement.

New rejections are made in view of further search and consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 31, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 8-10, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "preventing alopecia".

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: a) the breath of the claims; b) the nature of the invention; c) the state of the prior art, the level of one of ordinary skill; d) the level of predictability in the art; e) the amount of direction provided by the inventor; f) the existence of working examples; and g) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

The breath of the claims:

The breath of the instant claim broadly encompasses total prevention of alopecia regardless of cause or types by orally administering a composition comprising at least 21.7 % of taurine, hypotaurine, and/or salts thereof. The quantity of the active ingredient administered is irrespective of the condition of the patient taking the drug.

The nature of the invention:

The present invention is directed to a method of preventing alopecia by orally administering a composition comprising at least 21.7 % of taurine, hypotaurine, and/or salts thereof.

The state of the prior art

Prior art teaches that alopecia is caused by various underlying factors. These causes include genetic disorder, hormonal imbalance, nutritional deficiency, stress, chemotherapy, drugs, and x-ray therapy, etc. See US 6344448 B1, col. 2, lines 43-54. It is also well known that identification of cause of loss involves evaluating patient history and physical examination, which include obtaining information regarding drugs, major illnesses, weight loss or gain, major stress occurrences, as well as family background for genetic evaluation. See Id.

The level of predictability in the art;

Given the wide-ranging underlying causes of hairloss, whether prevention of alopecia via oral administration of taurine, hypotaurine, and/or its salts would be effective would be highly unpredictable because it is not known whether the amino acid would effectively treat or prevent all underlying causes of the hairloss (stress, hormonal dysfunction, chemical or radiation therapy, etc.).

The amount of direction provided by the inventor

Applicant's specification indicates that the present invention is directed to treating hairloss caused by aging, among other factors causing alopecia. See p. 1, line 13- p. 2, line 3; p. 5, lines 5-26.

The existence of working examples;

Example 26 illustrates a test result of study of women of certain age group having thin hair. There is no working example to enable the presently claimed prevention of hairloss.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

The burden of enabling the prevention of a physiological condition (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such conditions.

In conclusion, the specification does not provide guidance as to how one skilled in the art would go about preventing those patients susceptible to hairloss within the scope of the presently claimed invention. This particularly is true because, at the time of the present invention, prior arts indicated that hairloss is caused by numerous underlying factors that would be patient specific; thus whether the present invention would effectively prevent alopecia for all patients at all time is highly unpredictable. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing alopecia among the patients. The specification fails to enable "prevention", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the prevention of alopecia.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim recites "the oral composition comprises at least 21.7 wt % of the taurine, hypotaurine, and/or salts thereof". The original disclosure does not seem to support the new weight limitation of "at least 21.7 wt %" of taurine, hypotaurine, and/or salts thereof.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-13, 15, 19, 20, 21, 26, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada et al. (JP 2002-097116, Machine translation) in view of Kung (US 5639785) and McCarty (US 5582839).

Hamada teaches that taurine acts as a cellular activator for regulating hair cells and discloses hair-stimulating compositions for topical application.

Hamada fails to teach oral administration of taurine.

Kung teaches pharmaceutical compositions of isoflavanoid derivatives (polyphenols) for the treatment of male pattern baldness and alopecia areata, and in promoting the conversion of gray hair to the original pigment in hair follicles. See abstract. The reference indicates that it is well known and conventional practice in pharmaceutical art to administer active compounds in various routes via oral and topical

formulations, among others. See col. 4, lines 31-46. Specific types of formulations including tablets, capsules, powders, soft gels, solutions, emulsions, creams or ointments are mentioned. The reference teaches that both topical and oral administration of Minoxidil and daidzein treat baldness. See col. 1, lines 16-29. As for the dosage and the effective amount of daidzein, the reference indicates that the quantity will vary depending on the patient and the mode of administration. The reference indicates that from about 0.001-20 mg/kg of body weight of the patient per day may be used to achieve the desired effect. See col. 4, lines 46-56.

While Hamada and Kung do not specifically disclose orally administrable form of taurine, oral formulation of a highly soluble mineral salt of taurine, such as magnesium taurate, is already well known in pharmaceutical art. See McCarty, col. 3, lines 5-23.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teaching of Hamada by formulating orally administrable compositions as motivated by Kung because 1) Hamada teaches using taurine to treat alopecia; 2) Kung teaches that designing both topical and oral formulations of anti-alopecia compounds such as Minoxidil and diadzien is well known in the art; and 3) McCarty teaches that oral administration of taurine salt already has been in practice.

As for the suitable amount of taurine in the composition, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, prior arts provides general condition of making the drug since Hamada teaches a suitable amount of taurine in topical formulation in treating alopecia and Kung and McCarty teach oral formulation. Given these teachings, discovering an optimal weight of the active ingredient would have been within the skill of the art.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-13, 15, 19, 20, 21, 26, 39-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/
Primary Examiner, Art Unit 1611